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aMERICA AND THE BSE SCARE:

NEAR MISSES, FUTURE LESSONS

*by Kannon K. Shanmugam**

— The public buys its opinions as it buys its meat, or takes in its milk, on the principle that it is cheaper to do this than to keep a cow. So it is, but the milk is more likely — to be watered.”

On March 28, 1996, I paid the strangest visit of my life to a McDonald’s. Ordinarily, it would be impossible to walk into the McDonald’s in downtown Oxford, England, at dinnertime without encountering hundreds of tourists, screaming children, and local teenagers. On this day, however, where there would usually be hundreds of people, there were only two. Only two, because there were no hamburgers. In fact, in a throwback to the old Soviet Union, there were just two items on the menu: chicken and fish. The Burger King up the street was no different. A day later, I walked past the normally buzzing Angus Steakhouse outside Victoria Station in London, only to find it closed. At the local supermarket, row upon row of freezer lay empty. On my flight back to the United States, British Airways offered chicken in place of the usual beef.

Britain had fallen prey to a food scare unprecedented in the last decade, if not generation. In the weeks that followed, the crisis surrounding “mad cow” disease would have truly worldwide implications, affecting the regulatory policies of virtually every industrialized nation. Today, the potential consequences of the disease, although perhaps not as great as originally feared, still demand attention at the highest level of government. In this paper, my goals are twofold: to place the development of the disease in its historical

context, and to examine the options faced by government regulators in attempting to stem its spread. The paper comprises four parts. In Part I, I briefly trace the historical background to the “mad cow” scare, from its origin in England to the present day. In Part II, I examine the American response to the disease, situating steps taken by the United States government in the broader context of simultaneous developments occurring around the world. In Part III, I outline proposals made this month by the Food and Drug Administration (FDA) to impose a complete ban on certain types of animal feed implicated in the spread of “mad cow” disease. Finally, in Part IV, I present possible criticisms of the latest FDA proposals, arguing that they are too narrow to deal with the threat of human infection from unforeseen species and too difficult to enforce. In addition, I present alternative proposals to address each of these concerns. I begin, though, not with policy prescriptions, but with the discovery of an obscure disease some 200 years ago.

I. History of TSEs

Transmissible spongiform encephalopathies (TSEs) are slowly progressive, degenerative diseases of the central nervous system. They have been found in a wide variety of animal species and are invariably fatal. Although symptoms of the disease differ somewhat from species to species, they include abnormalities of behavior, posture, and gait, and ultimate loss of neurological function.¹ The earliest discovered form of TSE was scrapie, a disease affecting sheep and goats that is known to have existed in Europe for more than 200 years² and in North America for at least fifty.³ The human analogue to scrapie, Creutzfeldt-Jakob Disease (CJD), seems to date from the 1920s, when a disease known as “subacute spongiform encephalopathy” was first cited in medical literature.⁴ Cases of CJD have been discovered around the world, with an annual inci-

¹ See Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed, 62 Fed. Reg. 552, 556–58 (1997) (to be codified at 21 C.F.R. pt. 589) (proposed Jan. 3, 1997) [hereinafter FDA Report].

² See *id.* at 556.

³ See *id.*

⁴ See Stephen F. Dealler & Richard W. Lacey, *Transmissible Spongiform Encephalopathies*, in 4 *ENCYCLOPEDIA OF MICROBIOLOGY* 299 (Joshua Lederberg ed., 1992).

dence of approximately one case per million of the population.⁵ Until recently, the disease almost exclusively struck the old,⁶ with ninety percent of victims dying within one year of the disease's onset.⁷

The "mad cow" saga began with the discovery of a new form of TSE in cattle, bovine spongiform encephalopathy (BSE). In 1985, dairy farmers in Britain began noticing symptoms in their cows similar to those of other TSEs, prompting an investigation by scientists from the British Ministry of Agriculture.⁸ In November 1986, the British Central Veterinary Laboratory identified BSE as a new disease.⁹ The British government initially did nothing,¹⁰ though government scientists started conducting epidemiological studies the following April.¹¹ Almost eighteen months later, in April 1988, the government finally took formal action, establishing a working party, headed by Oxford Zoology Professor Sir Richard Southwood, to assess the significance of the burgeoning epidemic.¹² Although the Southwood group's initial findings were never made public, the group appears to have been the first to trace the cause of BSE to a cheap cattle feed created from the carcasses of sheep stricken with scrapie.¹³ Consequently, the group recommended in June that infected animals and their milk be destroyed, BSE be added to the list of compulsorily notifiable diseases, and further research be conducted.¹⁴ The government eventually implemented these recommendations, first banning the use of animal feed made from cattle and sheep remains in July, then ordering the destruction of all infected cattle in August, and finally making BSE a notifiable disease in November.¹⁵ In its final report in February 1989, the Southwood group concluded that it was "most unlikely that BSE will have implications for human health,"¹⁶ predicting that the disease would strike 17,000 to 20,000 cattle before beginning to die

⁵ See FDA Report, *supra* note 1, at 557.

⁶ See *id.*

⁷ See *id.*

⁸ See Sean Poulter, *The Scare That Has Simmered for Years*, THE DAILY MAIL, Mar. 21, 1996, at 6.

⁹ See *id.*

¹⁰ See Emily Wilson, *Ten-Year Battle Against Scourge*, THE DAILY MIRROR, Mar. 21, 1996, at 4.

¹¹ See Andrew Pierce, *Ten Years Deciding if Beef Is Safe*, THE TIMES, Mar. 21, 1996.

¹² See Poulter, *supra* note 8, at 6.

¹³ See *id.*

¹⁴ See Pierce, *supra* note 11.

¹⁵ See *id.*

¹⁶ *Id.*

out in 1993.¹⁷ Despite the Southwood group's assessment that a link between BSE and TSEs in humans was remote, the government banned the use of cattle offal in human food in November 1989,¹⁸ although it later emerged that Britain continued to export tons of potentially contaminated cattle meal to France until 1991.¹⁹ Meanwhile, at least eighteen nations imposed restrictions on cattle imports from Britain, including all eleven other members of the European Community.²⁰

Fears of a potential link between BSE and CJD began to become prevalent in 1990. On January 8, the British Ministry of Health announced a research program to investigate an apparent increase in the number of deaths in Britain from CJD.²¹ The announcement sparked immediate speculation about a link between BSE and CJD, with a May Gallup poll showing that more than 40% of British households were cutting back on beef consumption or eliminating it altogether as a result.²² To assuage these concerns, then-Agriculture Minister John Gummer held an infamous press conference, later criticized by the opposition Labor Party,²³ in which he fed a hamburger to his four-year-old daughter, Cordelia.²⁴ At the same time, leading scientists began to speculate about the risk of transspecies transmission of TSEs. As early as May 13, 1990, Professor Richard Lacey, a one-time government adviser who resigned after his warnings about an earlier salmonella outbreak were ignored, called for the slaughter of six million cows to prevent the transmission of TSEs to humans.²⁵ Fears were heightened by the confirmation of the first-ever case of TSE in a domestic cat.²⁶

Between 1990 and 1996, BSE temporarily faded from the headlines, with comparatively few developments relating to the disease. In 1993, Peter Warhurst, a dairy farmer whose herd had been affected by BSE, died

¹⁷ See Poulter, *supra* note 8, at 6.

¹⁸ See Wilson, *supra* note 10, at 4.

¹⁹ See *French Furor Over British Exports of Feed Linked to Mad Cows*, N.Y. TIMES, June 14, 1996, at A11.

²⁰ See Marianne McGowan, *Disease Killing British Cattle*, N.Y. TIMES, Jan. 24, 1990, at C13. Interestingly, this seems to have been the first article about BSE to appear in a major American newspaper.

²¹ See Poulter, *supra* note 8, at 6.

²² See *Beef off the Menu After Mad Cow Scare*, THE SUNDAY TIMES, May 20, 1990.

²³ See 274 PARLIAMENTARY DEBATES (HOUSE OF COMMONS) 376 (Mar. 20, 1996) (statement of Shadow Health Minister Harriet Harman).

²⁴ See Poulter, *supra* note 8, at 6.

²⁵ See Richard Palmer & Ian Birrell, *Leading Food Scientist Calls for Slaughter of Six Million Cows*, THE SUNDAY TIMES, May 13, 1990.

²⁶ See *id.*

of CJD,²⁷ the first case of CJD in which the victim was known to have been exposed to BSE.²⁸ Meanwhile, by March 1993, the number of cattle struck by BSE had risen to 87,000²⁹ — more than four times the worst-case prediction of the Southwood group. A year later, Germany urged the European Community to impose a complete ban on British beef after two cases of BSE were reported in cattle imported from Britain to Germany.³⁰ In July, the British government announced that traces of BSE had been found for the first time in tissues outside the nervous systems of cattle, giving rise to further fears that British beef was contaminated.³¹ Although BSE generally remained out of the headlines during this period, fears steadily grew to such a level that, when *The Sunday Times* surveyed fifty leading scientists in December 1995, forty-seven refused to rule out the possibility of a link between BSE and CJD.³²

Until 1996, politicians in the British government consistently denied any link between BSE and CJD.³³ However, disturbing developments in research on the BSE-CJD connection eventually forced the government to take action, as chronicled by a compelling article in *The Sunday Times*.³⁴ By the end of 1995, researchers at the National CJD Surveillance Unit had discovered six cases of an apparently new strain of CJD (–new variant” CJD, or nv-CJD), which struck primarily children and young adults rather than the old.³⁵ The new strain differed from the old one in three regards. First, the new strain was characterized by flower-shaped deposits of abnormal protein in the brain.³⁶ Also, victims of the new strain suffered from anxiety and depression, in addition to the usual symptoms of CJD victims.³⁷ Finally, and most ominously, all of the victims were beefeaters.³⁸ In February 1996, the number of cases of nv-CJD grew to eight, compelling the researchers

²⁷ See Wilson, *supra* note 10, at 4.

²⁸ See Poulter, *supra* note 8, at 6.

²⁹ See Wilson, *supra* note 10, at 4.

³⁰ See Sean Ryan, *Germans Urge Euro Ban on British Beef*, THE SUNDAY TIMES, Mar. 13, 1994.

³¹ See Sean Ryan & Rajeev Syal, *Beef Sales Drop by £10 Million in New ‘Mad Cow’ Scare*, THE SUNDAY TIMES, July 3, 1994.

³² See Steve Connor & Simon Reeve, *Scientists Voice New Beef Doubts*, THE SUNDAY TIMES, Dec. 3, 1995.

³³ See, e.g., Poulter, *supra* note 8, at 6.

³⁴ See Steven Connor & Michael Prescott, *BSE*, THE SUNDAY TIMES, Mar. 24, 1996.

³⁵ See *id.*

³⁶ See *id.*

³⁷ See *id.*

³⁸ See *id.*

to alert the government's most senior scientific advisers.³⁹ The Spongiform Encephalopathy Advisory Committee duly called an urgent meeting for March 8.⁴⁰ At that meeting, the researchers presented slides of their findings, as "[t]he committee watched in stunned silence."⁴¹ The committee reconvened on March 16 and concluded, after two days of discussion, that the most likely explanation for nv-CJD was exposure to BSE.⁴² On March 18, the committee notified the responsible ministers, who immediately contacted Prime Minister John Major.⁴³ The next morning, Major convened an emergency meeting, where it was decided that Health Minister Stephen Dorrell — regarded as an adept politician and even a potential future Prime Minister⁴⁴ — should break the news to the public.⁴⁵ The full Cabinet granted its approval the morning of March 20, clearing the way for an announcement in Parliament the same afternoon.⁴⁶ Meanwhile, during the four days it took the committee and the government to decide upon a course of action, two more cases of nv-CJD were reported, bringing the total number to ten.⁴⁷

At exactly 3:30 p.m. on March 20, Dorrell strode into the House of Commons and delivered the following statement:

With permission, Madam Speaker, I should like to make a statement about the latest advice that the government have received from the Spongiform Encephalopathy Advisory Committee.... There remains no scientific proof that bovine spongiform encephalopathy can be transmitted to man by beef, but the committee has concluded that the most likely explanation at present is that [the nv-CJD] cases are linked to exposure to BSE before the introduction of the specified bovine offal ban in 1989.⁴⁸

At first glance, this statement seems innocuous enough: after all, Dorrell stressed that there was “no scientific proof” of a link between BSE and nv-CJD, and that any exposure to BSE occurred before the 1989 offal

³⁹ See *id.*

⁴⁰ See *id.*

⁴¹ *Id.*

⁴² See *id.*

⁴³ See *id.*

⁴⁴ See Philip Webster & Arthur Leathley, *Dorrell Raises the Starter's Flag in Race for Succession*, THE TIMES, Jan. 3, 1997.

⁴⁵ See Connor & Prescott, *supra* note 34.

⁴⁶ See *id.*

⁴⁷ See *id.*

ban. But rather than focusing on these points, speakers in the ensuing debate zeroed in on the suggestion that a BSE-CJD link was the “most likely explanation” for the new nv-CJD cases. In her response, Shadow Health Minister Harriet Harman of the Labor Party charged that the government was giving “yet more false reassurance”.⁴⁹

If the facts are not fully disclosed, the public response will be fear, which will then be stoked up by ignorance and innuendo.... I appreciate that the position is difficult and the information uncertain, but it is clear that the Secretary of State [Dorrell] has lost the confidence of the British people.⁵⁰

Later on the same day, Agriculture Minister Douglas Hogg — who had been disqualified from giving the statement on the possible BSE-CJD link because he was seen as insufficiently telegenic⁵¹ — announced the immediate implementation of a ban on the use of mammalian tissue in animal feed.⁵²

Reading through the transcript, one is struck by the relatively measured tone of the parliamentary debate. It is thus all the more surprising that the British public reacted with a frenzy verging on outright panic. In addition to the typically sensationalistic tabloids, even the mainstream press carried banner headlines the next morning proclaiming the advent of an epidemic.⁵³ *The Guardian*, one of Britain’s five “quality” dailies, carried the subheadline, “Many millions in potential danger.”⁵⁴ At least two newspapers reported on an appearance by Professor John Pattison, chair of the Spongiform Encephalopathy Advisory Committee, on BBC’s *Newsnight* program, in which he warned that he could not rule out the possibility of up to 500,000 cases of nv-CJD per year.⁵⁵ Of the “quality” dailies, only *The Daily Telegraph* — generally considered the

⁴⁹ 274 PARLIAMENTARY DEBATES (HOUSE OF COMMONS) 376 (Mar. 20, 1996) (statement of Shadow Health Minister Harriet Harman).

⁵¹ See Connor & Prescott, *supra* note 34.

⁵² See 274 PARLIAMENTARY DEBATES (HOUSE OF COMMONS) 387 (Mar. 20, 1996) (statement of Agriculture Minister Douglas Hogg).

⁵³ See, e.g., Kevin Maguire & David Bradshaw, *EPIDEMIC*, THE DAILY MIRROR, Mar. 21, 1996, at 2.

⁵⁴ Paul Brown et al., *Beef Warning Sparks Panic*, THE GUARDIAN, Mar. 21, 1996, at 1.

⁵⁵ See, e.g., Caroline Davies et al., *Beef Linked to Brain Disease*, THE DAILY TELEGRAPH, Mar. 21, 1996, at 1; Maguire & Bradshaw, *supra* note 53, at 2.

most sympathetic to the government — reported Dorrell’s statement that there was “no scientific proof” of a BSE-CJD link.⁵⁶ However, it exaggerated the import of his statement, reporting that he had said that “scientists had not discovered *absolute* proof of the link,” rather than that *no* such proof yet existed.⁵⁷ Arguably, it was this press-driven hysteria, as much as the British government statement, that triggered immediate reaction around the world. On March 21, five European countries imposed bans on British beef imports, with Germany renewing its call for a pan-European ban.⁵⁸ In addition, about one-third of British schools announced they were taking beef off the menu.⁵⁹ Over the following week, several countries joined the ban,⁶⁰ and all of Britain’s major fast-food chains announced that they would no longer serve British beef.⁶¹ As the public abandoned beef in droves, the government seemed undecided about what to do next. Speaking on the BBC’s flagship radio news program, *Today*, the morning after the announcement, Dorrell said that the government was considering the wholesale slaughter of Britain’s cattle.⁶² However, on March 25, Hogg said that the safeguards then in place were sufficient.⁶³ Perhaps in response to the British government’s indecision, the European Commission, acting on the recommendation of a European veterinary committee, imposed a worldwide ban on all exports of British beef and beef byproducts, ranging from medicine to candy.⁶⁴ In early May, in an attempt to convince the European Commission to lift the ban, the British government began slaughtering approximately 15,000 to 20,000 cattle per week.⁶⁵ However, in September, the government again reversed course, virtually halting the slaughter after new evidence from Oxford scientists suggested that the BSE outbreak would run its course by 2001.⁶⁶ In October, British

⁵⁶ See Davies et al., *supra* note 56, at 1.

⁵⁷ *Id.* (emphasis added).

⁵⁸ See John Darnton, *British Beef Banned in France and Belgium*, N.Y. TIMES, Mar. 22, 1996, at A8.

⁵⁹ See *id.*

⁶⁰ See John Darnton, *British Beef Sales Plunge as Germany and Italy Join Import Ban*, N.Y. TIMES, Mar. 23, 1996, — 1, at 3.

⁶¹ See John Darnton, *London Adamant as European Nations Ban British Beef*, N.Y. TIMES, Mar. 26, 1996, at A3.

⁶² See Darnton, *supra* note 58, at A8.

⁶³ See Darnton, *supra* note 61, at A3.

⁶⁴ See John Darnton, *Europe Orders Ban on Exports of British Beef*, N.Y. TIMES, Mar. 28, 1996, at A1.

⁶⁵ See Sarah Lyall, *Britain Begins Killing Cows but Slow Pace Irks Farmers*, N.Y. TIMES, May 4, 1996, — 1, at 5.

⁶⁶ See Warren Hoge, *British Call Halt to Cow Slaughter Demanded by European Union*, N.Y. TIMES, Sept. 20, 1996, at

researchers published new findings suggesting that nv-CJD was closer in molecular structure to BSE than to the old strain of CJD, thus providing more evidence of a link between BSE and nv-CJD.⁶⁷ Perhaps because of this discovery, and after renewed pressure from the European Commission, the government again changed its mind in December, reinstating the full planned slaughter of 1.3 million head.⁶⁸

Ironically, despite the public hysteria since March, the growth in the number of new cases of nv-CJD has actually slowed somewhat in recent months: only five new cases have been reported in Britain since March, bringing the overall total to fifteen.⁶⁹ In addition, French doctors have diagnosed at least one case, and possibly a second, of the new strain.⁷⁰ No cases have been confirmed anywhere else in the world.⁷¹

II. The American response

Initially, the Department of Agriculture (USDA), rather than the Food and Drug Administration (FDA), took the lead in coordinating the American response to the BSE scare. The earliest official action regarding BSE came in July 1989, when the USDA, following their counterparts in several other countries, imposed a ban on the importation of live ruminants and ruminant products from Britain.⁷² Although consistent with the actions of other countries, this ban had little practical effect: perhaps due to its comparative self-reliance in beef production, the United States had imported only 499 head of cattle from Britain in the years leading up to the ban.⁷³ Worryingly in retrospect, however, there appears to have been some confusion about the

A11.

⁶⁷ See John Collinge et al., *Molecular Analysis of Prion Strain Variation and the Etiology of 'New Variant' CJD*, 383 NATURE 685 (1996).

⁶⁸ See Warren Hoge, *Major, Feeling Political Heat, Plans to Step Up Slaughter of Cows*, N.Y. TIMES, Dec. 17, 1996, at A15.

⁶⁹ See *Fifteenth Case of New Variant Creutzfeldt-Jakob Disease Reported By British Health Officials*, FOOD CHEMICAL NEWS, Jan. 13, 1997, at 23.

⁷⁰ See J.P. Deslys et al., *New Variant Creutzfeldt-Jakob Disease in France*, 349 THE LANCET 30 (1997).

⁷¹ See *France Reports Second Case of Illness Linked to Cows*, N.Y. TIMES, Nov. 1, 1996, at A13.

⁷² See FDA Report, *supra* note 1, at 563.

⁷³ See Lawrence K. Altman, *U.S. Officials Confident That Mad Cow Disease of Britain Has Not Occurred Here*, N.Y. TIMES, Mar. 27, 1996, at A12.

scope of the ban. In 1990, a spokeswoman for the USDA told the *New York Times* that, although the United States had banned the import of *live* cattle, it still imported small amounts of canned beef from Britain — which conceivably could have been contaminated with BSE.⁷⁴ However, on the heels of the British panic in 1996, the USDA said that no *processed* beef or live cattle had been imported from Britain since 1989 — a rather broader claim.⁷⁵ In any event, in the absence of more sweeping government action, the American beef industry took matters into its own hands: the National Renderers Association and the Animal Protein Producers Industry imposed a voluntary industrywide ban on the use of adult sheep offal in feed for ruminant (cud-chewing) animals.⁷⁶ However, data collected a few years later by the FDA suggests that this ban was widely disregarded.⁷⁷

Between 1989 and 1992, the USDA continued to serve as the primary American agency investigating BSE. In 1990, the Animal and Plant Health Inspection Service (APHIS), an arm of the USDA, established the BSE Issues Management Team to analyze the risk of a BSE outbreak in the United States.⁷⁸ In addition, APHIS itself assumed several responsibilities in the battle against BSE, including examining the brains of dead cattle for signs of the disease: as of earlier this month, more than 5,000 brains had been examined, with no sign of BSE in any of them.⁷⁹ In 1991, APHIS issued a report analyzing the risks of TSE transmission from scrapie-infected sheep.⁸⁰ Acting upon the report, APHIS subsequently imposed a ban on the importation of products made from certain types of ruminant tissue, including meat meal, bone meal, blood meal, offal, fat, and glands.⁸¹ APHIS also continued to control flocks of sheep for scrapie, as it had done since 1952,⁸² and

⁷⁴ See McGowan, *supra* note 20, at C13.

⁷⁵ See John Darnton, *Britain Ties Deadly Brain Disease to Cow Ailment*, N.Y. TIMES, Mar. 21, 1996, at A1.

⁷⁶ See Letter from F.D. Bisplinghoff, National Renderers Association, to Animal Protein Producers (1989).

⁷⁷ See Food and Drug Administration, Report of Findings of Directed Inspections of Sheep Rendering Facilities (1993).

⁷⁸ See FDA Report, *supra* note 1, at 562.

⁷⁹ See *id.* at 563.

⁸⁰ See Animal and Plant Health Inspection Service, Qualitative Analysis of BSE Risk Factors in the United States (1991).

⁸¹ See Importation of Animal Products and Byproducts From Countries Where BSE Exists, 56 Fed. Reg. 63865 (1991) (to be codified at 9 C.F.R. pts. 94–95).

⁸² See FDA Report, *supra* note 1, at 563.

issued updated reports on the risk of a BSE outbreak in the United States.⁸³ Meanwhile, in 1990, the Office Internationale Epizootics (OIE) became the first international health organization to take action, holding meetings to consider ways of stemming the spread of BSE.⁸⁴ The OIE would continue to hold meetings up to, and after, the British scare of 1996.⁸⁵

The FDA first became involved in the regulation of BSE in 1992. On December 9, Dr. Fred Shank, Director of the Center for Food Safety and Applied Nutrition, wrote a letter to manufacturers of dietary supplements after the FDA discovered that certain supplements contained brain, glands, and nervous tissue from cattle and sheep.⁸⁶ In the letter, Shank advised that manufacturers pursue a two-prong strategy to eliminate potential BSE in their products, investigating the sources of any beef or sheep tissues to see if they were produced in countries with TSE outbreaks and reformulating products with TSE-free tissues.⁸⁷ In the letter, however, Shank took pains to emphasize that there was “no proven link” between animal and human TSEs,⁸⁸ and acknowledged that securing assurances that animal tissues were TSE-free would be “difficult.”⁸⁹ In 1993, Dr. Jane Henney, FDA Deputy Commissioner for Operations, wrote a similar letter to manufacturers of drugs, biological drugs, medical devices, and biological device products.⁹⁰ Henney went one step further than Shank in his corresponding letter of a year earlier, recommending that manufacturers not only identify the sources of any bovine tissues used in their products, but also maintain traceable records for each lot of such materials, documenting the country of origin of any live animal used to produce them.⁹¹ Although the letter carried no rulemaking force, the final sentence warned that all records kept on the recommendation

⁸³ See Animal and Plant Health Inspection Service, Bovine Spongiform Encephalopathy: Implications for the United States (1993).

⁸⁴ See FDA Report, *supra* note 1, at 564.

⁸⁵ See *id.*

⁸⁶ See Letter from Fred Shank, Director, Center for Food Safety and Applied Nutrition, to Manufacturers of Dietary Supplements (Nov. 9, 1992), *reprinted in* Bovine Derived-Materials; Agency Letters to Manufacturers of FDA-Regulated Products, 59 Fed. Reg. 44591, 44591–92 (1994) [hereinafter Agency Letters].

⁸⁷ See *id.* at 44592.

⁸⁸ *Id.*

⁸⁹ See *id.*

⁹⁰ See Letter from Jane E. Henney, Deputy Commissioner for Operations, Food and Drug Administration, to Manufacturers of FDA-Regulated Products (Dec. 17, 1993), *reprinted in* Agency Letters, *supra* note 86, at 44592–93.

⁹¹ See *id.*

of the letter should be –available for FDA inspection.”⁹² Finally, in 1994, Linda Suydam, Henney’s interim successor, wrote two more advisory letters, to manufacturers of FDA-regulated products for animals and manufacturers of dietary supplements and cosmetics respectively.⁹³ In the first letter, Suydam essentially extended Henney’s recommendations for manufacturers of human drugs to manufacturers of animal feed and drugs, advising them to maintain a paper trail for all materials of bovine origin.⁹⁴ In the second letter, Suydam applied almost the same rule to manufacturers of dietary supplements — thus greatly expanding the recommendations of the 1992 Shank letter — and of cosmetics.⁹⁵ However, for the first time in an FDA letter, Suydam attached a list of types of cattle tissue, classifying each type according to the suspected level of infectivity.⁹⁶ The clear implication was that manufacturers who used tissues from the lower –categories” of infectivity were less likely to be hounded for failure to comply with the letter’s recommendations.

In 1994, the FDA made its first foray into rulemaking on BSE, publishing a set of proposed rules that would have banned the use in ruminant feed of sheep and goat offal made from certain tissues.⁹⁷ The FDA found that such offal was no longer generally recognized as safe (GRAS) due to the link between scrapie and BSE,⁹⁸ and therefore proposed to reclassify such offal as a food additive for the purpose of regulation under the Food, Drug, and Cosmetic Act.⁹⁹ The rules would have applied only to sheep and goats over the age of twelve months, because of the comparative scarcity of scrapie in younger animals.¹⁰⁰ Overall, this proposal seemed far from aggressive: after all, Britain had implemented a wholesale ban on the use of all cattle and sheep remains in 1988 and had further banned the use of cattle offal in human food products in 1989, acting

⁹² *Id.* at 44593.

⁹³ See Letter from Linda A. Suydam, Interim Deputy Commissioner for Operations, Food and Drug Administration, to Manufacturers of FDA-Regulated Products for Animals (Aug. 17, 1994), *reprinted in* Agency Letters, *supra* note 86, at 44593; Letter from Linda A. Suydam, Interim Deputy Commissioner for Operations, Food and Drug Administration, to Manufacturers and Importers of Dietary Supplements and Cosmetics (Aug. 17, 1994), *reprinted in* Agency Letters, *supra* note 86, at 44593–94.

⁹⁴ See Letter to Manufacturers of FDA-Regulated Products, *supra* note 93, at 44593.

⁹⁵ See Letter to Manufacturers and Importers, *supra* note 93, at 44593–94.

⁹⁶ See *id.* at 44594.

⁹⁷ See Substances Prohibited From Use in Animal Food or Feed; Specified Offal From Adult Sheep and Goats Prohibited In Ruminant Feed, 59 Fed. Reg. 44584 (1994) (to be codified at 21 C.F.R. pt. 589) (proposed Aug. 29, 1994).

⁹⁸ See *id.* at 44587.

⁹⁹ See *id.*

¹⁰⁰ See *id.* at 44588.

on much less scientific evidence on the links between various types of TSEs.¹⁰¹ Despite the relative modesty of the FDA's proposed rules, however, they never went into force. Why not? At least three explanations obtain. First, the proposal was immediately opposed by large segments of the agricultural industry, which were presumably concerned about the cost of purchasing or producing other types of offal.¹⁰² Second, FDA risk-assessment studies — amazingly, with the benefit of hindsight — suggested that the proposed rules would have no real value in reducing the risk of a BSE outbreak in the United States.¹⁰³ Third, the FDA apparently was concerned about not having enough inspectors to enforce the proposed ban.¹⁰⁴ Consequently, although federal officials during this period trumpeted the fact that no cases of BSE had yet been detected in the United States,¹⁰⁵ they omitted to mention that they had imposed far fewer safeguards than had their British counterparts.

Despite the dearth of action by government agencies to prevent a BSE outbreak in the United States, government officials were quick to provide assurances in the wake of the British panic in March 1996. On March 21, the day after the British announcement of a possible link between BSE and CJD, Agriculture Secretary Dan Glickman and Dr. Will Hueston, the leading USDA expert on BSE, appeared on the Cable News Network to play down the likelihood of an American BSE outbreak.¹⁰⁶ Hueston said that the United States had pursued a “very proactive program of surveillance” against BSE and had already acted to minimize the risk of BSE being introduced into the country.¹⁰⁷ For his part, Glickman said, “We are on top of it and we’re doing our best to insure that this does not spread anywhere in the world.”¹⁰⁸ In retrospect, these assurances seem at best overconfident. For one thing, the United States had taken absolutely no action to prevent the spread of BSE to other countries, as Glickman had claimed. In addition, the supposedly

¹⁰¹ See *supra* p. 4.

¹⁰² See Altman, *supra* note 73, at A12.

¹⁰³ See *id.*

¹⁰⁴ See Lawrence K. Altman, *WHO Seeks Barriers Against Cow Disease*, N.Y. TIMES, Apr. 4, 1996, at A12.

¹⁰⁵ See, e.g., Altman, *supra* note 73, at A12.

¹⁰⁶ See *EarlyPrime* (Cable News Network television broadcast, Mar. 21, 1996).

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

–proactive” American program of surveillance against BSE had consisted merely of keeping close tabs on British cattle imports — and apparently not on imports of cattle from countries that had themselves had BSE outbreaks as a result of British imports — and inspecting the carcasses of dead animals for signs of the disease. However, due to the lengthy incubation period of BSE and the unavailability of any tests for BSE while animals were still alive, such inspections would have been unable to detect an outbreak until it had already reached epidemic proportions.

Although government officials put on a brave face in public, they rushed into action behind the scenes. On March 22, just a day after Glickman and Hueston went on television to reassure American consumers, officials from the USDA, FDA, and the Centers for Disease Control and Prevention (CDC) met to discuss the ramifications of the British announcement.¹⁰⁹ The meeting appears to have been the first interagency meeting involving both USDA and FDA officials since the disease was originally diagnosed some ten years earlier. However, the officials took no immediate action, pending a meeting called by the World Health Organization (WHO) for April 2 and 3. At that meeting, held in conjunction with the OIE, a group of international experts recommended that all countries ban the use of ruminant tissues in ruminant feed to prevent the further introduction of TSEs into cows.¹¹⁰ The experts also advised that milk and gelatin were safe, due to the intransmissibility of BSE through either product.¹¹¹ However, the experts made no recommendations on the possible transmission of TSEs from cows to humans: in 1995, the WHO had recommended a meeting in the fall of 1996 to discuss the possible link between BSE and CJD, but no date was ever set.¹¹²

¹⁰⁹ See *id.*

¹¹⁰ See FDA Report, *supra* note 1, at 564.

¹¹¹ See *id.*

¹¹² See Altman, *supra* note 73, at A12.

Between the USDA-FDA meeting and the WHO conference, confusion reigned among the American government agencies, with action occurring on no fewer than three fronts. In late March, the USDA convened a meeting of its own, involving seventy animal and public-health experts from the United States.¹¹³ In stark contrast to the WHO conference, however, the USDA meeting, after reviewing current policies, did not recommend any further safeguards, except that the number of post-mortem examinations of cattle for BSE be increased.¹¹⁴ For its part, the FDA, acting independently from the USDA, announced on March 29 that it would expedite regulations barring all ruminant tissue from ruminant feed.¹¹⁵ The livestock industry and veterinary groups immediately imposed a voluntary ban on such feed.¹¹⁶ Finally, state officials began to take action against the few remaining head of British cattle in the United States: by early April, twenty-one states had destroyed, or begun negotiations to purchase and destroy, cattle imported from Britain before the 1989 ban, despite the fact that the none of the imported animals had shown any sign of BSE.¹¹⁷

On April 8, almost three weeks after the British parliamentary statement, American government officials held another interagency meeting — this time involving not just the FDA, USDA, and CDC, but also the National Institutes of Health (NIH) and, curiously, the Department of Defense (DoD).¹¹⁸ The purpose of the meeting was twofold: to disseminate information about the WHO meeting, and to coordinate preventative activities on both the BSE and CJD fronts.¹¹⁹ However, the meeting was closed to the public, and the only result of the meeting appears to have been a decision by the CDC to increase surveillance for CJD in four target states: California, Connecticut, Minnesota, and Oregon.¹²⁰ Federal officials then took no further steps for more than a month, until the FDA and APHIS convened a third interagency meeting, an international

¹¹³ See *id.*

¹¹⁴ See *id.*

¹¹⁵ See Altman, *supra* note 104, at A12.

¹¹⁶ See *id.*

¹¹⁷ See *Thirteen Cattle Quarantined in Mad Cow Disease*, N.Y. TIMES, Apr. 10, 1996, at B4.

¹¹⁸ See FDA Report, *supra* note 1, at 564.

¹¹⁹ See *id.*

¹²⁰ See Lawrence K. Altman, *Four States Watching for Brain Disorder*, N.Y. TIMES, Apr. 9, 1996, at C12.

symposium on the transmission of TSEs.¹²¹ At the symposium, officials and experts discussed findings from unpublished and ongoing scientific investigations on TSEs, as well as possible approaches to managing the risk of TSEs in animals.¹²²

After nearly two months of relative government inactivity, the FDA took its first official action in early May. On May 10, Dr. Michael Friedman, Deputy Commissioner for Operations, announced in a statement to the Subcommittee on Human Resources and Intergovernmental Relations — apparently the first testimony by an FDA official before Congress on TSEs — that the FDA would shortly release an advanced notice of proposed rulemaking (ANPRM) on the use of ruminant tissues in ruminant feed.¹²³ On May 14, the ANPRM was duly published in the Federal Register.¹²⁴ In the brief four-page notice, the FDA requested submissions on some eighteen specific topics, including scientific information on the occurrence of TSEs, data on the amount of feed that may contain ruminant tissue, evidence of the potential economic consequences of regulatory action, estimates of the cost of compliance, and suggestions of possible alternative actions that could be taken to combat the spread of TSEs.¹²⁵ Although the ANPRM did not contain any concrete regulatory proposals, the language of the notice clearly indicated that the FDA was contemplating an outright ban on ruminant-to-ruminant feed.¹²⁶

In the months following the ANPRM, government activity waned as BSE faded from the headlines. In December, the FDA announced the formation of a TSE working group, comprising the Deputy Commissioner for Operations and representatives from each of its five centers.¹²⁷ In addition, the interagency BSE

¹²¹ See FDA Report, *supra* note 1, at 562.

¹²² See *id.*

¹²³ See *Protecting the U.S. Consumer From Food Borne Illnesses: Hearings Before the Subcomm. on Human Resources and Intergovernmental Relations of the House Comm. on Gov't Reform and Oversight*, 104th Cong. (1996) (statement of Michael Friedman, Deputy Commissioner for Operations, Food and Drug Administration).

¹²⁴ See Substances Prohibited From Use in Animal Food or Feed; Protein Derived From Ruminants Prohibited in Ruminant Feed, 61 Fed. Reg. 24253 (1996) (to be codified at 21 C.F.R. pt. 589) (proposed May 14, 1996).

¹²⁵ See *id.* at 24254–55.

¹²⁶ See *id.* at 24253.

¹²⁷ See *TSE Threat Prompts Formation of FDA-Wide Working Group*, FOOD CHEMICAL NEWS, Dec. 23, 1996, at 41.

Policy Planning and Issue Management Group, formed in the wake of the April meeting between the FDA, USDA, and other departments, announced plans to meet this month to finalize a new response plan to the BSE scare.¹²⁸ However, federal officials took no further action until January 2, when the FDA proposed comprehensive new rules to prevent the spread of TSEs.¹²⁹

III. The FDA proposal

The FDA evidently timed the announcement of its proposal for maximum media effect, releasing it during the traditionally slow news period between the holidays and the inauguration of a new Congress. On January 2, top officials from the FDA and its responsible Cabinet department, the Department of Health and Human Services (HHS), fanned out to promote the new plan. In a press release, HHS Secretary Donna Shalala said of the proposal, –It will add another level of safeguards to protect the U.S. against the potential risk from [TSEs].”¹³⁰ For his part, outgoing FDA Commissioner David Kessler told the *New York Times*: –We are creating a fire wall, a barrier. If a case occurred in this country, the steps would confine the disease to the individual animal and prevent secondary spread.”¹³¹ He added in a HHS press release that the proposed rules would –greatly decrease the potential risk to humans.”¹³²

The thirty-two-page proposal represents the United States government’s most comprehensive published document on TSEs, and thus merits close scrutiny. After a brief introduction, the report begins with a detailed examination of the scientific and historical background to the crisis.¹³³ In addition to scrapie in sheep and BSE in cattle, the proposal examines the origins of TSEs in other animals, such as mink, deer, zoo animals,

¹²⁸ See *id.*

¹²⁹ See FDA Report, *supra* note 1.

¹³⁰ *FDA Proposes Precautionary Ban Against Ruminant-to-Ruminant Feeding*, *HHS News* (January 2, 1997) [hereinafter HHS Press Release].

¹³¹ Lawrence K. Altman, *FDA Proposal Would Ban Using Animal Tissue in Feed*, *N.Y. TIMES*, Jan. 3, 1997, at A14.

¹³² HHS Press Release, *supra* note 130.

¹³³ See FDA Report, *supra* note 1, at 556–65.

and cats.¹³⁴ Usefully, the report also includes a comprehensive history of human TSEs.¹³⁵ While obviously focusing on the old and new variants of CJD, the proposal also considers some more obscure forms of human TSEs, including Gertsman-Strausler-Scheinker Syndrome, a genetically transmitted but less progressive strain of CJD, and Kuru, a bizarre variant of CJD that seems to have occurred only in members of a remote cannibalistic tribe in Papua New Guinea.¹³⁶ The proposal then examines the etiology of TSEs, concluding that the disease probably crossed the species barrier via an infectious protein, or “prion.”¹³⁷ The FDA notes that TSEs are most likely transmitted orally, although genetic factors may also play a role, to judge from specific mutations commonly found in CJD sufferers.¹³⁸ Finally, the report cites studies showing that it is difficult to render TSEs non-infectious: ominously, TSEs appear to be unresponsive to radiation or ultraviolet light, although preliminary results indicate that ordinary processing of tissues containing TSEs may have some effect.¹³⁹

Next, the proposal examines the relationship between the various types of TSEs.¹⁴⁰ The FDA cites British studies to support the generally accepted theory, as discussed above,¹⁴¹ that BSE arose when cattle were given feed containing sheep tissue contaminated with scrapie.¹⁴² Curiously, however, according to the FDA, similar studies in the United States were unable to confirm this effect, raising the possibility that BSE may have developed spontaneously.¹⁴³ Having considered the likely relationship between scrapie and BSE, the report then examines the possible link between BSE and CJD.¹⁴⁴ The proposal traces the scientific genesis of the theory, from the British announcement to the latest research demonstrating the close similarities in

¹³⁴ See *id.* at 556–57.

¹³⁵ See *id.* at 557–58.

¹³⁶ See *id.*

¹³⁷ See *id.* at 558–59.

¹³⁸ See *id.* at 559.

¹³⁹ See *id.* at 560.

¹⁴⁰ See *id.* at 560–61.

¹⁴¹ See *supra* p. 3.

¹⁴² See FDA Report, *supra* note 1, at 560.

¹⁴³ See *id.*

¹⁴⁴ See *id.* at 560–61.

structure between BSE and nv-CJD.¹⁴⁵ Finally, the proposal notes that certain tissues from sheep and cattle — namely, brain, spinal cord, and retina — appear to be more highly infective than others, with no evidence that muscle meat, milk, or blood can transmit TSEs at all.¹⁴⁶

Next, the proposal examines the potential risk of a BSE outbreak in the United States.¹⁴⁷ Citing the “devastating effect” an epidemic would have on animal health and the American farm industry, the FDA argues that a “conservative regulatory approach” is justified.¹⁴⁸ However, the FDA takes pains to note that no cases of BSE or nv-CJD have yet been detected in the United States.¹⁴⁹ In addition, the proposal maintains that certain conditions that may have contributed to the BSE epidemic in Britain are not present in the United States: namely, a higher rate of incidence of scrapie, less sophisticated feed processing, and greater use of meat and bone meal in feed for young cattle.¹⁵⁰ This section of the proposal ends with a rather self-congratulatory history of the American regulatory response to the BSE scare: the FDA lauds the USDA for its “proactive and preventive” actions to keep BSE out of the country and omits any reference to the fact that its 1994 proposal was withdrawn in the face of heavy criticism.¹⁵¹

In the second major section of the report, the FDA briefly surveys the statutory authority for its proposed ban on ruminant-to-ruminant feed.¹⁵² First, it notes that the term “food,” as defined in section 201(f) of the Food, Drug, and Cosmetic Act, has traditionally been read to include animal feed.¹⁵³ Consequently, under the same analysis used for human food products, the FDA argues that any material intended for use that “results or may reasonably be expected to result in its becoming a component of food” constitutes a food additive unless it is either GRAS or the subject of a prior sanction.¹⁵⁴ According to the FDA, this doctrine

¹⁴⁵ See *id.* at 561.

¹⁴⁶ See *id.*

¹⁴⁷ See *id.* at 561–62.

¹⁴⁸ *Id.* at 561.

¹⁴⁹ See *id.* at 561–62.

¹⁵⁰ See *id.* at 562.

¹⁵¹ *Id.* at 562–64.

¹⁵² See *id.* at 565–66.

¹⁵³ See *id.* at 565.

¹⁵⁴ *Id.*

provides a mechanism for regulating the introduction of animal tissues into animal feed: in the absence of a prior sanction, by declaring that those tissues are not longer GRAS, the FDA can regulate them like any other kind of food additive and even, as proposed in this report, ban them altogether.¹⁵⁵

Having dispensed rather summarily with the potential statutory difficulties, the report next presents a selection from the nearly 600 comments made in response to the FDA's ANPRM, issued some eight months earlier.¹⁵⁶ The respondents fell into two distinct — and predictable — groups. On the one hand, consumer groups, pharmaceutical firms, scientists, and veterinarians all favored the proposed regulatory action, citing the prophylactic effect on human health, the British experience, and the potential harm to the United States economy from a BSE scare.¹⁵⁷ Other supporters of the proposal cited the need to maintain consumer confidence in the beef and dairy industry, even if the risk of an actual outbreak in the United States was comparatively small.¹⁵⁸ On the other hand, renderers, meatpackers, feed companies, and farmers opposed the proposed action.¹⁵⁹ They cited the apparent absence of BSE in the United States, the lack of scientific data to support a ban, environmental concerns, potential problems with enforcement, and the likely economic hardship that would be suffered by both producers and consumers of ruminant-based feed products.¹⁶⁰ In addition, they argued that, if the FDA were to impose a ban at all, it should prohibit only the use of those tissues that have been demonstrated to be infective, rather than the use of all ruminant tissues.¹⁶¹

In the next major section of the report, the FDA outlines several alternative approaches to the proposed ruminant-to-ruminant ban.¹⁶² As suggested by opponents to the proposal, the FDA could impose only a

¹⁵⁵ See *id.* at 566.

¹⁵⁶ See *id.* at 566–67.

¹⁵⁷ See *id.* at 567.

¹⁵⁸ See *id.* at 567.

¹⁵⁹ See *id.* at 566. See also *TSE Threat*, *supra* note 127, at 42 (detailing industry criticisms of the FDA proposal).

¹⁶⁰ See FDA Report, *supra* note 1, at 566–67.

¹⁶¹ See *id.* at 567.

¹⁶² See *id.* at 567–69.

partial ruminant-to-ruminant ban, essentially prohibiting just the use of the brain, eyes, spinal cord, and distal ileum in animal feed.¹⁶³ This proposal would have the advantage of comporting with the latest scientific data, since there appears to be no evidence that other ruminant tissues can transmit TSEs; however, it would also have the disadvantage of being exceedingly difficult to enforce, since there is currently no way to identify with any certainty what types of tissue are contained in a given sample of feed.¹⁶⁴ Second, the FDA could apply a broader ban on all mammal-to-ruminant feed.¹⁶⁵ As I shall suggest later in this paper, this proposal would have advantages in ensuring greater protection and enhancing enforceability; however, the likelihood of TSE transmission from non-ruminant mammals is, at least at present, comparatively small.¹⁶⁶ Third, the FDA could bar the use in feed of tissues from only those species of mammals in which an American outbreak of TSE has been conclusively established.¹⁶⁷ This proposal, essentially a variant on the partial ruminant-to-ruminant ban advocated by the industry, would eliminate the use of parts of sheep, goats, mink, deer, and elk, but not cattle; the principal drawback is that, were BSE to be proven to occur spontaneously (that is, via mutation), parts of BSE-infected cattle could make their way into animal feed unimpeded, thus triggering an epidemic.¹⁶⁸ Fourth, the FDA could bar only sheep and goat offal from ruminant feed.¹⁶⁹ This proposal would be arguably the easiest to enforce, but would suffer the same drawback as the prior proposal: namely, it would not guard against the entry of spontaneous BSE into the food chain.¹⁷⁰ Finally, the FDA could simply take no action.¹⁷¹ Of course, this would be the cheapest option to implement, but would offer no additional protection against a BSE outbreak.¹⁷²

¹⁶³ See *id.* at 567–68.

¹⁶⁴ See *id.* at 568.

¹⁶⁵ See *id.*

¹⁶⁶ See *id.*

¹⁶⁷ See *id.*

¹⁶⁸ See *id.*

¹⁶⁹ See *id.* at 568–69.

¹⁷⁰ See *id.*

¹⁷¹ See *id.* at 569.

¹⁷² See *id.*

Next, the report lays out the FDA’s proposed rule for a complete ruminant-to-ruminant ban.¹⁷³ Subsection (a) of the rule essentially excludes blood, milk, and gelatin from the ruminant proteins covered by the ban, since those substances have been proven to be unable to transmit TSEs.¹⁷⁴ Subsection (a) also defines the scope of the regulation: all renderers, protein blenders, feed manufacturers, and distributors are subject to the rule.¹⁷⁵ Subsection (b) declares, as suggested in the statutory-authority section of the proposal,¹⁷⁶ that protein derived from ruminant tissues is not GRAS when intended for use in animal feed.¹⁷⁷ In subsection (c), the FDA creates requirements for those renderers who are unable to separate ruminant from non-ruminant materials.¹⁷⁸ These renderers must place warning labels on their products, indicating the possibility that the products may contain ruminant tissues.¹⁷⁹ In addition, they must maintain copies of the sales invoices for all of their products, to ensure that purchasers of those products are not using them to make animal feed.¹⁸⁰ The subsection also provides incentives for renderers to develop either a method of deactivating TSEs or a test to detect their presence.¹⁸¹ Subsection (d) establishes regulatory requirements for protein blenders, feed manufacturers, and distributors who, like the renderers in subsection (c), are unable to separate ruminant from non-ruminant materials.¹⁸² These parties are subject to the same requirements as the renderers in subsection (c), except that parties able to purchase “clean” feed from renderers who have developed tests for deactivation or detection are exempt from the requirements.¹⁸³ Subsection (e) sets standards for renderers, blenders, manufacturers, and distributors who can separate ruminant from non-ruminant materials.¹⁸⁴ These parties are subject to the same requirements as under subsections (c) and (d), but can obtain an exemption

¹⁷³ See *id.* at 570–71.

¹⁷⁴ See *id.* at 570.

¹⁷⁵ See *id.*

¹⁷⁶ See *supra* pp. 23–24.

¹⁷⁷ See FDA Report, *supra* note 1, at 570.

¹⁷⁸ See *id.*

¹⁷⁹ See *id.*

¹⁸⁰ See *id.*

¹⁸¹ See *id.*

¹⁸² See *id.*

¹⁸³ See *id.* at 571.

¹⁸⁴ See *id.*

for their non-ruminant products if they can certify that there was no blending of ruminant and non-ruminant materials during processing.¹⁸⁵ Subsection (f) establishes rules for feed users, requiring them only to make available to FDA inspectors copies of the relevant invoices and labels.¹⁸⁶ Subsection (g) establishes that feed in violation of the previous provisions of the rule is deemed to be either adulterated or mislabeled for purposes of the Food, Drug, and Cosmetic Act.¹⁸⁷ Finally, subsection (h) requires that records be kept for at least two years before being discarded.¹⁸⁸

In a brief section, the proposal then considers the possible environmental consequences of the various alternatives.¹⁸⁹ The report notes that, were there to be no outbreak of BSE in the United States, the “no action” alternative would, not surprisingly, have the fewest environmental ramifications.¹⁹⁰ According to the FDA assessment, the proposed ruminant-to-ruminant ban would have moderate environmental effects, due to the increased use of landfills for now-unused ruminant materials.¹⁹¹ However, the FDA argues that these effects would be merely temporary, since the cattle markets would quickly adjust to the increased demand for non-ruminant materials, thus leading to a decrease in the production of ruminants for use in animal feed.¹⁹² The report then considers the possible environmental ramifications were there to be a BSE outbreak.¹⁹³ The report reasons that the “no action” alternative would have severe environmental consequences, since large numbers of cattle would need to be destroyed and disposed of.¹⁹⁴ However, under the FDA’s somewhat circular reasoning, the ruminant-to-ruminant ban would have minimal environmental effects, since the spread of BSE would be tightly controlled.¹⁹⁵

¹⁸⁵ *See id.*
¹⁸⁶ *See id.*
¹⁸⁷ *See id.*
¹⁸⁸ *See id.*
¹⁸⁹ *See id.* at 572.
¹⁹⁰ *See id.*
¹⁹¹ *See id.*
¹⁹² *See id.*
¹⁹³ *See id.*
¹⁹⁴ *See id.*
¹⁹⁵ *See id.*

In the final major section of the proposal, the FDA analyzes the potential economic impact of the proffered alternatives.¹⁹⁶ The FDA engages in standard cost-benefit analysis to gauge the merits of the various options, reasoning that the benefits of the proposed ruminant-to-ruminant rule would include the reduced need to destroy an estimated 300,000 head of cattle in the event of an outbreak, reduced risk to public health, reduced direct livestock losses, reduced costs of future regulation, and reduced losses in domestic sales and exports due to a drop in consumer confidence.¹⁹⁷ Overall, although the FDA does not give a precise figure, it estimates that these losses would total in the billions of dollars, with the destruction of BSE-exposed livestock costing some \$3.7 billion alone.¹⁹⁸ However, for the purpose of cost-benefit analysis, any such figure must obviously be discounted by the probability of an outbreak, which the FDA does not estimate — presumably for fear that disclosing any such number would spark negative public reaction. On the cost side, the FDA calculates the total cost of the proposed rule to renderers, distributors, and users.¹⁹⁹ In its somewhat complicated analysis, the FDA breaks down costs into seven categories: capital costs, operating and disposal costs, transportation, documentation, substitution costs, losses in revenue to renderers, and gains in revenue to producers of non-ruminants.²⁰⁰ Under the FDA’s worst-case market-impact scenario, the mammal-to-ruminant ban would be the most expensive (\$56.5 million), followed by the proposed ruminant-to-ruminant ban (\$48.3 million), the partial ruminant-to-ruminant ban (\$27.4 million), the TSE-carrier-to-ruminant ban (\$9.3 million), and the sheep-and-goat-to-ruminant ban (\$300,000).²⁰¹ Perhaps more interesting are the FDA’s figures on the potential losses to the rendering industry, which range from \$305.6 million for the mammal-to-ruminant ban to just \$100,000 for the sheep-and-goat-to-ruminant ban.²⁰² However, the FDA’s analysis is again incomplete, since it omits any reference to the increased enforcement costs that the FDA,

¹⁹⁶ See *id.* at 572–78.

¹⁹⁷ See *id.* at 573–76.

¹⁹⁸ See *id.* at 575.

¹⁹⁹ See *id.* at 576–78.

²⁰⁰ See *id.* at 576.

²⁰¹ See *id.*

²⁰² See *id.*

and presumably state agencies, would bear as a result of any of these bans. The proposal concludes with a comprehensive list of references to government documents and scientific articles on TSEs.²⁰³

IV. Analysis of the FDA proposal

The FDA's ruminant-to-ruminant ban represents the most sweeping action yet proposed by a government agency to deal with the threat of a BSE outbreak in the United States. However, I believe that it does not go far enough. In this section, I shall outline two potential objections to the proposal and suggest alternative approaches that would provide significantly greater protection to the American people with only minimal, if any, additional cost.

The first objection that can be levied against the FDA proposal is that it is underprotective. Although the most threatening form of TSE at the moment is undoubtedly BSE, TSEs have been found in non-ruminant mammals, such as minks, as well as in ruminants.²⁰⁴ While the FDA proposal is not explicit on this point, it implies that there would be no risk of infection under a ruminant-to-ruminant ban because mink tissue is not used in animal feed.²⁰⁵ However, this reasoning is at best shortsighted. In recent years, TSEs have shown a remarkable, and disturbing, ability to cross species lines: the first case of bovine TSE was diagnosed just over ten years ago, the first case of feline TSE only seven years ago, and the first case of the new strain of human TSE less than two years ago.²⁰⁶ Given that some non-ruminant species would still be used in animal feed under a ruminant-to-ruminant ban — indeed, undoubtedly in larger quantities, as producers switch from ruminant to non-ruminant tissues to maintain protein levels in feed — the possibility of TSEs appearing in those species, and then entering the food chain, presents a real threat. Under a mammal-to-ruminant ban

²⁰³ See *id.* at 579–82.

²⁰⁴ See *id.* at 557.

²⁰⁵ See *id.* at 568.

²⁰⁶ See *supra* pp. 3, 5, 6.

— one of the alternatives considered and then discarded by the FDA — such a possibility would evaporate. In view of the FDA’s stated desire to pursue a “conservative regulatory approach” due to the uncertainty surrounding the risk of a BSE outbreak,²⁰⁷ the broader mammal-to-ruminant ban makes all the more sense.

In addition to the very real advantage of preventing the entry of as-yet-undiscovered varieties of TSEs into the food chain, a mammal-to-ruminant ban may actually be cheaper to implement than the FDA’s proposed ruminant-to-ruminant ban. The FDA rightly suggests that renderers would suffer somewhat larger losses as a result of a mammal-to-ruminant ban.²⁰⁸ However, these losses may well be offset by other gains. First, a mammal-to-ruminant ban would be easier to enforce. At present, as the FDA acknowledges, there is no way of determining whether feed contains ruminant or non-ruminant materials.²⁰⁹ However, tests do exist to establish whether feed contains mammalian or non-mammalian proteins.²¹⁰ Second, a mammal-to-ruminant ban, unlike a ruminant-to-ruminant one, would require no change to the current labeling system, which uses definitions devised by the Association of American Feed Control Officials.²¹¹ Third, a mammal-to-ruminant ban would eliminate the risk that feed intended for ruminants would be accidentally mixed with feed meant for non-ruminants, which could still contain potentially contaminated ruminant tissue.²¹² Indeed, just such a risk of contamination largely motivated Britain’s decision to apply a similar mammal-to-ruminant ban in the wake of last year’s public panic.²¹³ Fourth, a mammal-to-ruminant ban would be easier for the industry to implement. At least three industry groups pointed out that the segregation of ruminant and non-ruminant tissues, as required by the FDA proposal, would be impractical due to the regular commingling of protein products from the two categories.²¹⁴ Fifth and finally, a mammal-to-ruminant ban would introduce less

²⁰⁷ FDA Report, *supra* note 1, at 561.

²⁰⁸ *See id.* at 576.

²⁰⁹ *See id.* at 565.

²¹⁰ *See id.* at 568.

²¹¹ *See id.*

²¹² *See id.*

²¹³ *See id.*

²¹⁴ *See id.*

instability in the commodity markets for animal protein, which are apparently very volatile.²¹⁵

The FDA proposal is also underprotective because it fails to provide adequately for the development of better diagnostics to detect TSEs. At present, the only way to confirm the presence of BSE is by autopsy, with the result that it is difficult to isolate cases of BSE with any certainty.²¹⁶ The same is true for the new strain of CJD, although British researchers announced earlier this month that they have begun to develop a simple diagnostic test that could be used on suspected nv-CJD victims while still alive.²¹⁷ To be sure, the current FDA proposal aims to encourage the development of such diagnostics, but only indirectly: as noted above, the proposal would allow any firm that can develop and implement a demonstrably successful diagnostic test to be exempt from the requirements of the new regulation.²¹⁸ However, this provision would have only comparatively small incentive effects, since the benefit of exemption would be little more than the foregone cost of increased recordkeeping. Instead, the FDA, perhaps in conjunction with the USDA and Congress, should directly fund research aimed at developing better diagnostics. To offset the cost of such funding, Congress could pass a “BSE tax” on animal feed, with feed producers simply passing the cost of the tax on to consumers.

The second objection that can be raised against the FDA proposal is that it would be very hard, and perhaps impossible, to enforce. The proposal itself acknowledges this difficulty, stating with typical governmental euphemism, and not a little understatement, that the regulation of BSE “presents unique enforcement challenges.”²¹⁹ In the absence of a test to determine whether feed contains ruminant or non-ruminant materials, as discussed above,²²⁰ the FDA proposes to “rely on normal business records” as a means of

²¹⁵ See *id.*

²¹⁶ See *id.* at 552.

²¹⁷ See Andrew F. Hill et al., *Diagnosis of New Variant Creutzfeldt-Jakob Disease by Tonsil Biopsy*, 349 THE LANCET 99 (1997).

²¹⁸ See *supra* p. 27.

²¹⁹ FDA Report, *supra* note 1, at 569.

²²⁰ See *supra* p. 31.

checking compliance with the new rules.²²¹ However, this seems at best naïve. It would be child's play for a feed manufacturer, faced with the substantially higher cost of procuring non-ruminant instead of ruminant ingredients, to cut a deal with a ruminant-tissue producer, faced with a major loss of business as a result of the new rule. Indeed, it would make good economic sense for these parties to bargain in this fashion, since each would be better off under standard Coasian analysis. All that the parties would need to do is to forge the paperwork — which would be all the easier if the producer of the ruminant tissue being covertly sold has an overt non-ruminant-tissue operation as well.

Two other enforcement-related difficulties merit brief consideration. First, it is often difficult for renderers, from whom feed manufacturers obtain a substantial share of their ingredients, to separate ruminant from non-ruminant tissue. Independent renderers, in particular, use as raw materials everything from restaurant scraps to byproducts from multispecies slaughtering operations.²²² For these producers, separating ruminant from non-ruminant tissue, if not entirely impossible, may simply be economically unfeasible. Therefore, the effect of the proposed rules may be to drive these producers out of business altogether, thus pushing up the cost of non-ruminant tissue ingredients still further. Second, the FDA would almost certainly have to hire more inspectors to deal with the added burden of enforcing the new rule. To monitor compliance, inspectors will have to follow a paper trail from feed purchasers to the original farmers whose animals supplied the tissue used in the feed, which could take days or even weeks per case. In the absence of specific provisions to increase the number of inspectors, it is unclear how rigorously the new proposal will be enforced, thus undermining its potential deterrent effect.

Rather than attempting to enforce the proposed rule by checking paperwork, the FDA should establish criminal sanctions for any violation. Such sanctions could apply not just to renderers and feed manufacturers, but also to any farmer who uses feed containing ruminant tissue, whether knowingly or not. To be sure,

²²¹ FDA Report, *supra* note 1, at 569.

²²² *See id.*

there are at least three potential objections to such a proposal. First, given the fact that farmers using feed are analogous to consumers who are not generally subject to FDA sanctions, it could be argued that the mere use of a product does not constitute transmission in interstate commerce sufficient to invoke the FDA's statutory authority,²²³ though arguably the FDA could regulate animals to which ruminant feed is administered on the ground they are about to be introduced in interstate commerce.²²⁴ Second, it could be argued that the FDA does not have the authority to impose criminal sanctions in this context, though its right to do so in the context of directors of corporations has generally been upheld.²²⁵ Third, it could be argued that, even if the FDA does have the power to impose criminal sanctions, farmers should be protected by some form of scienter requirement, though such a requirement has frequently not been imposed.²²⁶ In any event, a powerful argument can be made in rebuttal to all three of these points. Even if the FDA does not have the statutory authority to impose such wide-ranging sanctions, Congress could pass a statute embodying both the FDA's proposed rule and tighter, criminal sanctions. Given the widespread public concern over BSE, such legislation might have a good chance at passage, despite the potential opposition of industry lobby groups.²²⁷ No matter how such sanctions are imposed, though, they would have a beneficial effect by placing the burden on the industry — rather than FDA inspectors — to ensure that feed products are safe. If farmers know they could be sent to jail for using feed containing ruminant products, they will take pains to extract guarantees from their suppliers that the feed they are purchasing is ruminant-free, and so on down the line. Such a rule would allow the FDA to save substantially on enforcement costs while simultaneously enhancing the proposed rule's deterrent effects.

²²³ See 21 U.S.C. — 334(a) (1994).

²²⁴ See *United States v. Seven Barrels, Etc., of Spray Dried Whole Egg*, 141 F.2d 767 (7th Cir. 1944).

²²⁵ See, e.g., *United States v. Park*, 421 U.S. 658 (1975); *United States v. Dotterweich*, 320 U.S. 277 (1943).

²²⁶ See PETER BARTON HUTT & RICHARD A. MERRILL, *FOOD AND DRUG LAW: CASES AND MATERIALS* (2d ed. 1991) 1163–64.

²²⁷ See *FDA Plans Public Hearings on Feed Ban Proposal; Critics Question Scope, Cost of Proposed Rule*, *FOOD CHEMICAL NEWS*, Jan. 13, 1997, at 3.

Conclusion

Overall, the BSE scare presents the perfect example of how *not* to manage a public-health crisis. On both sides of the Atlantic, governments reacted slowly and clumsily to increasingly disturbing scientific evidence, thus engendering public panic with its concomitant effects on consumer confidence. In the United States, in particular, government agencies were far too complacent in the face of unknown but potentially massive health risks. The FDA's recent proposal represents an admirable first step toward implementing adequate protections against the dangers of both presently known and as-yet-undiscovered forms of TSEs. However, they do not go far enough. The FDA should reissue the proposal with a broader scope, increased funding for diagnostics, and stiffer penalties for violation. Only then will we truly have learned our lessons from BSE.